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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,989	08/21/2001	Michael H.B. Stowell	06618-045002	8355

7590

02/04/2002

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EXAMINER

MULLIS, JEFFREY C

ART UNIT

PAPER NUMBER

1711

DATE MAILED: 02/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

T-D-3

Office Action Summary

Application No.

09/934,989

Applicant(s)

STOWELL ET AL.

Examiner

Jeffrey C. Mullis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Claims 3 and 8 lack periods. Correction is required.

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

d. Claims 4-8 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Claims 4-8 recite no process steps and therefore are drawn to a use.

e. Claims 1-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The term "small" is subjective and therefore unclear.

Claim 4 recites a "method of performing renal dialysis" yet recites no actual method steps of performing renal dialysis at all and it is therefore unclear what process steps are embraced by the process of claim 4.

The "said hybrid mixture" in claim 8 lacks antecedent basis in any preceding claim.

Claim 1 is unclear since the preamble of claim 1 recites a "method of preparing sol-gel encapsulated phospholipid vesicles" yet recites no process steps where a sol-gel is used or formed or in which a sol is used.

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Claim 6 recites a "sol", not a sol-gel and therefore claim 6 lacks antecedent basis in any preceding claim.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-7 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Williams (USP 5,843,474) in view of Wheatley et al. (USP 4,921,757).

Williams discloses the use of liposomes in renal dialysis. Note patent claim 2 in this regard.

Wheatley et al. disclose a composition containing a phospholipid which is used to produce a liposome followed by which encapsulation by crosslinked alginate takes place. Note the paragraph bridging columns 3 and 4. The agar encapsulating the lipid is said to be a "sol-gel" at column 10 lines 7-14. Cross-linking takes place via calcium ions at column 9 lines 40-44 and the product can therefore properly be said to be an "inorganic-organic hybrid" sol-gel. The composition is said to

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be an improvement over the prior art in giving a more steady release of materials at column 2 lines 35-50.

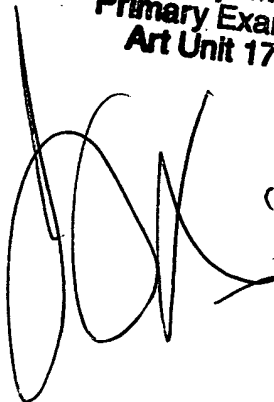
The primary reference does not disclose that the lipid vesicles which are used are specifically encapsulated by a sol-gel. However, use of a sol-gel encapsulated lipid vesicle would have been obvious to a practitioner having ordinary skill in the art at the time of the invention in the process of the primary reference as taught by the secondary reference Wheatley et al. in the expectation of improving the release rate of the liposomes in the process of Williams et al. absent any showing of surprising or unexpected results.

Any inquiry concerning this communication should be directed to Jeffrey Mullis at telephone number (703) 308-2820.

J. Mullis:cdc

February 1, 2002

Jeffrey Mullis
Primary Examiner
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A handwritten signature in black ink, appearing to be 'JM', is written over the printed name and title of the examiner.